

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,
v.

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

STIPULATION OF INFRINGEMENT BETWEEN PLAINTIFFS GILEAD SCIENCES, INC. AND EMORY UNIVERSITY AND DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.

WHEREAS Plaintiff Gilead Sciences Inc. and Emory University (“Plaintiffs”) are the holders of New Drug Application (“NDA”) No. 21-752 by which the FDA granted approval for Truvada® (emtricitabine and tenofovir disoproxil fumarate), a co-formulation of two reverse transcriptase inhibitors for the treatment of HIV-1 infection;

WHEREAS Defendant Mylan Pharmaceuticals Inc. (“Mylan”) has filed Abbreviated New Drug Application No. 20-6436 (the “Mylan ANDA”) for approval to manufacture and sell a generic version of Truvada® (“Mylan’s ANDA product”) prior to the expiration of U.S. patent Nos. 6,642,245 (“the ‘245 patent”) and 6,703,396 (“the ‘396 patent”);

WHEREAS Plaintiffs have asserted in this patent infringement suit that the filing of the Mylan ANDA infringes certain claims of the ‘245 and ‘396 patents;

NOW THEREFORE, the parties stipulate and agree as follows, subject to the approval of the Court.¹

1. Making, using, offering to sell, selling, or importing Mylan’s ANDA product (unless the specification for emtricitabine provided in Mylan’s ANDA is materially amended to change the enantiomeric purity of such emtricitabine relative to its corresponding (+) enantiomer in a manner relevant to the asserted claims, (hereinafter “a material amendment” or “materially amended”)) in/into the United States would directly infringe claims 1, 3-5, 13, 15, and 16 of the ‘396 patent, unless a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that each patent claim is invalid or not enforceable.

¹ This Stipulation is limited to the claims and defenses related to the ‘245 and ‘396 patents, and is independent of the parties’ claims and defenses related to U.S. Patent Nos. 8,592,397 and 8,716,264.

2. Making, using, offering to sell, selling, or importing Mylan's ANDA product (unless the specification for emtricitabine provided in Mylan's ANDA is materially amended) with the proposed labeling in/into the United States would actively induce infringement of claim 6 of the '245 patent, unless a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent claim is invalid or not enforceable.

3. Plaintiffs will not assert patent claims other than those listed above regarding the '245 and '396 patents in this or any other litigation involving Mylan's ANDA, unless Mylan's ANDA is materially amended.

4. Mylan will not assert in this litigation that patent claims other than those listed above regarding the '245 and '396 patents are invalid or unenforceable. However, to the extent that asserted claims depend from unasserted claims (e.g., claim 6 of the '245 patent), Mylan may argue invalidity of any such unasserted claims as necessary to support its arguments that the asserted claims are invalid.

5. Plaintiffs will not seek discovery from Mylan related to the issue of infringement of the '245 and '396 patents. Mylan will not seek discovery from Plaintiffs related to the issue of infringement of the '245 and '396 patents.

6. Nothing in this stipulation shall preclude Mylan from asserting any invalidity defense against the asserted claims of the '245 and '396 patents in this present lawsuit.

7. Nothing in this Stipulation shall preclude Plaintiffs from asserting the above-listed patent claims or any other patent claims in future litigation arising from any material amendment to the Mylan ANDA or any future applications that Mylan files with the FDA.

8. Nothing in this Stipulation shall preclude Mylan from asserting any defenses, including non-infringement and invalidity, against all claims in any litigation (including this litigation) in connection with any material amendment to the Mylan ANDA or any future applications that Mylan files with the FDA.

9. Mylan shall produce to Plaintiffs any material amendment to its ANDA at the same time it files such material amendment. Plaintiffs reserve the right to reopen discovery in the event of such material amendment.

<p>Dated: June 29, 2015</p> <p><u>/s/ William J. O'Brien</u> Thomas Krzeminski (<i>pro hac vice</i>) thomas.krzeminski@knobbe.com William O. Adams (<i>pro hac vice</i>) william.adams@knobbe.com Karen Cassidy (<i>pro hac vice</i>) karen.cassidy@knobbe.com KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502</p> <p>William R. Zimmerman (<i>pro hac vice</i>) bill.zimmerman@knobbe.com Jay R. Deshmukh (<i>pro hac vice</i>) jay.deshmukh@knobbe.com Christopher C. Kennedy (<i>pro hac vice</i>) chris.kennedy@knobbe.com KNOBBE, MARTENS, OLSON & BEAR, LLP 1717 Pennsylvania Avenue, NW, Suite 900 Washington, DC 20006 Telephone: (202) 640-6400 Facsimile: (202) 640-6401</p>	<p>Respectfully submitted,</p> <p><u>/s/ Chad L. Taylor</u> Colleen Tracy (CT 8377) MAYER BROWN LLP 1675 Broadway New York, NY 10019</p> <p>David B. Bassett (DB 8727) WILMER CUTLER PICKERING HALE AND DORR LLP 7 World Trade Center 250 Greenwich Street New York, NY 10007</p> <p>Christopher Borello (CB 6164) FITZPATRICK, CELLA, HARPER & SCINTO 1290 Avenue of the Americas New York, NY 10104</p> <p>Frank E. Simmerman, Jr. (WVSB# 3403) Chad L. Taylor (WVSB# 10564) SIMMERMAN LAW OFFICE, PLLC 254 E. Main St. Clarksburg, WV 26301-2170 Phone: (304) 623-4900 Fax: (304) 623-4906 <i>Attorneys for Plaintiffs Gilead Sciences, Inc. and Emory University</i></p>
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